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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/705,686	11/10/2003	Leif N. Bowman	047711-0331	4638

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EXAMINER

STIGELL, THEODORE J

ART UNIT PAPER NUMBER

3763

DATE MAILED: 06/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/705,686

Applicant(s)

BOWMAN ET AL.

Examiner

Theodore J. Stigell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 November 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>2/23/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 15-18, 26, and 28 are rejected under 35 U.S.C. 102(b) as being anticipated by Marggi (6,302,866).

Marggi clearly discloses an infusion set that includes all of the limitations as recited in claim 1. See Figures 1-6 and the respective portions of the specification. Marggi discloses an infusion set with a base (2), a cannula (1) connected to the base, and a removable connector (3) and tubing (5) attached to the base (2). The connector does not have a great capability to rotate on the base but can conceivably rotate a few degrees in either direction if enough pressure is exerted on the handles of the connector (3). There is a continuous passage from the tubing to the cannula when the connector (3) is attached to the base (2).

In regards to claim 2, Marggi clearly discloses an infusion set that includes all of the limitations as recited in claim 1 wherein the base (2) comprises a barrier (6) that extends away from the surface.

In regards to claim 3, Marggi clearly discloses an infusion set that includes all of the limitations as recited in claim 2 wherein the connector (3) comprises a stop (7) extending away from the surface of the connector (3).

In regards to claim 4, Marggi clearly discloses an infusion set that includes all of the limitations as recited in claim 3 wherein the barrier (6) restricts the movement of the stop (7).

In regards to claims 26, Marggi clearly discloses an infusion set that includes all of the limitations as recited in claim 1 wherein the rotation of the connector is usually limited to no rotation.

In regards to claims 15 –18 and 28, Marggi clearly discloses an infusion set that includes all of the limitations as recited in claim 15. Marggi discloses an infusion set with a base (2) having a receiving area, a cannula (1) connected to the base, and a removable connector (3) and tubing (5) attached to the base (2). The connector does not have a great capability for angular movement but can conceivably move a few degrees in either direction if enough pressure is exerted on the handles of the connector (3). In regards to claim 28, the connector is normally limited to no rotation. There is a continuous passage from the tubing to the cannula when the connector (3) is attached to the base (2). The base (2) comprises a member (6) that extends away from the surface and restricts the movement of a second member (7) on the connector (3).

Claims 1-3, 5-7, 10-17, 19-21, 24-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Mathiasen (5,980,506).

Mathiasen clearly discloses an infusion set that includes all of the limitations as recited in claims 1-3, 5-7, and 26. See Figures 1-6 and the respective portions of the specification. Mathiasen discloses an infusion set with a base made up of elements (1) and (8), a cannula (2) affixed to the base, a connector (3) removably attached to the base, and tubing (4) affixed to the connector (3). A fluid passage is provided from the tubing (4) to the cannula (2). The base portion has a barrier (7) that extends away from the surface of the base portion. The connector has a stop (5) that extends away from the connector portion. The connector (3) has a limited rotation on the base element (8) that can be restricted by the base element (8). The rotation of the connector can be anywhere from no rotation to 180 degrees.

Mathiasen clearly discloses a method of using an infusion set as recited in claims 10-14 and 27. The inherent use of the device disclosed by Mathiasen meets the limitations of the method disclosed by the Applicant. The base (8) is positioned at an infusion site and the connector (3) is attached to the base (8). The position of the connector (3) and the tubing (4) can then be adjusted to any angle between 0-180 degrees by the user.

In regards to claims 15-17, 19-21, and 28, Mathiasen discloses an infusion set that includes all of the limitations. Mathiasen discloses an infusion set with a base made up of elements (1) and (8), a cannula (2) affixed to the base, a connector (3) removably attached to the base, and tubing (4) affixed to the connector (3). A fluid passage is provided from the tubing (4) to the cannula (2). The base portion has member (7) that extends away from the surface of the base portion. The connector (3)

has a second member (5) that extends away from the connector portion. The angular movement of the connector (3) can be restricted by the base element (8) to any angle between no rotation and 180.

In regards to claims 24-25, Mathiasen discloses an infusion set that includes all of the limitations as recited in claim 24. Mathiasen discloses the use of an adhesive to position the base at the site of infusion as is well known in the art of infusion sets. Mathiasen also discloses a locking means including elements 5, 16, 17, and 11 that connects the connector (3) and a part of the base (1). Mathiasen also discloses a means for adjusting the positioning of the tubing by rotating element (1) on the shaft (6) in the grooves (7). The tubing can be limited to any degree between no rotation and 180 degrees by the user.

Claims 1,8,9,15,22, and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell (5,545,143).

Fischell clearly discloses an infusion set that includes all of the limitations as recited in claims 1. See Figures 9,10, and 13 and the respective portions of the specification. Fischell discloses an infusion set that includes a base (210) with a cannula (227) attached to the base (210), a removable connector (240) and tubing (243) attached to the base. The connector (240) does not have a great capability to rotate, but can conceivably rotate a few degrees in either direction if enough pressure is applied. A continuous passage is provided from the tubing (243) to the cannula (227).

In regards to claims 8 and 9, Fischell discloses an infusion set that includes all of the limitations as recited in claims 1 wherein the infusion set includes a needle hub

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(150) with a needle (88) and a needle cover (114). Fischell also discloses the use of an adhesive pad (230) to anchor the set to the skin of a patient.

In regards to claim 15, Fischell discloses an infusion set that includes all of the limitations. Fischell discloses an infusion set that includes a base (210) having a receiving area (203), a cannula (227) attached to the base (210), a removable connector (240) and tubing (243) attached to the base. The connector (240) does not have a great capability for angular movement, but can conceivably rotate a few degrees in either direction if enough pressure is applied. A continuous passage is provided from the tubing (243) to the cannula (227).

In regards to claims 22 and 23, Fischell discloses an infusion set that includes all of the limitations as recited in claims 1 wherein the infusion set includes a needle hub (150) with a needle (88) and a needle cover (114). Fischell also discloses the use of an adhesive pad (230) to anchor the set to the skin of a patient.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 4645495 A to Vaillancourt
US 4743231 A to Kay
US 4755173 A to Konopka
US 4813939 A to Marcus
US 4955861 A to Enegren
US 5176662 A to Bartholomew
US 5257980 A to Van Antwerp
US 5522803 A to Teissen-Simony
US 5607407 A to Tolkoff
US 6017328 A to Fischell
US 6123690 A to Mejslov
US 6290677 B1 to Arai


US 6355021 B1 to Nielsen
US 6461329 B1 to Van Antwerp
US 6572586 B1 to Wojcik
US 6579267 B2 to Lynch
US 6736797 B1 to Larsen

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TS


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